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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,433	11/30/2001	Kazuma Tomizuka	014643-012110US	9190

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	4

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/000,433	Applicant(s) TOMIZUKA ET AL.	
	Examiner Q. Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-11 are drawn to a transgenic non-human mammal comprising two human immunoglobulin loci, light and heavy chain loci. Classified in Class 800, subclass 13.

II. Claims 1-11, 71, and 72 are drawn to a transgenic non-human mammal comprising two human immunoglobulin loci, light and heavy chain loci; and further comprises a mutation of a gene that increases the immune response to autoantigen. Classified in Class 800, subclass 13.

III. Claims 12-16, 20-28, 36-44, 66-69, 73, 74, 77-82 are drawn to a method comprising immunizing a transgenic non-human mammal, and collecting B cells from the animal to form hybridomas, hybridoma cells obtained, and collecting human sequence antibodies from the hybridoma.. Classified in class 435, subclass 70.1.

IV. Claims 12, 17, 18, 20-28, 43, 45, 46, 73, 74, 81, 82 are drawn to a method comprising immunizing a transgenic non-human mammal comprising two human immunoglobulin loci, light and heavy chain loci, and collecting *nucleic acid* sequences encoding human antibodies. Classified in class 536, subclass 23.53.

V. Claims 19, 55-65, 83-88 are drawn to a method of producing a human antibody comprising expressing a nucleic acid encoding an antibody sequence in a host cell in vitro or phage display library. Classified in class 435, subclass 69.1

VI. Claims 29-35, 43, 75, 76 are drawn to a method of generating human antibody comprising immunizing a transgenic non-human mammal, and collecting antibodies from the mammal. Classified in class 424, subclass 184.1.

VII. Claims 47-54 are drawn to nucleic acids encoding the heavy and light chain variable region, vectors comprising and expressing the nucleic acids, host cells comprising the nucleic acid, and a method of obtaining nucleic acids from cultivated host cells. Classified in class 435, subclass 91.1, 320.1 and 455.

VIII. Claim 70 is a human antibody having an IgA isotype. Classified in class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups II and I is drawn to a different product, i.e. different transgenic animals. The different transgenic mammals are distinct in genomic structures as well as modes of operation such as when used in producing antibodies. For example, the transgenic mammal whose genome comprises a gene mutation in Fc-gamma IIB is more efficient in producing auto-antibody.

Inventions II, III, VII, VIII, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case, each of the groups I-III, VII, and VIII is drawn to a different product, i.e. nucleic acids, antibodies, hybridomas, and transgenic mammals. The different products are distinct in chemical structure and function, as well as modes of operation, and belong to different chemical entities.

Inventions IV-VII, and III are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to different methods of obtaining hybridoma cells, antibodies, and nucleic acid sequences, and generating antibodies by different means. The different methods use material different substances, have different method steps, different modes of operation, and have distinct technical considerations. For example, the antibody could be produced by direct isolation from the immunized animal (group VI), from a hybridoma cell (group III), or expressed by a vector expressing the coding sequences (group V).

Inventions III, IV, VI, and I / II could be related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transgenic animal could be used in a materially different process such as for producing B cells, for obtaining antibodies, for obtaining nucleic acids, or for breeding.

Inventions III, IV, VI, and VIII could be related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the processes of groups III, IV, VI, could be used to make a structurally different antibody, and the antibody of group VIII could be made by different methods, such as using a hybridoma, an expression vector, or chemical synthesis.

The differences of the Inventions I-VIII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Inventions I-IV and VI encompass patentably distinct species of non-human transgenic mammals whose genome comprising two human immunoglobulin loci, wherein the heavy chain locus is of a transchromosome and the light chain locus is associated with an endogenous chromosome, or wherein the light chain locus is of a transchromosome and the heavy chain locus is associated with an endogenous chromosome. If one of the inventions I-IV and VI is elected, further election of a species is necessary.

Inventions III, IV, and VI further encompass patentably distinct species, i.e. using patentably distinct transgenic non-human mammals of group I or II. If one of the inventions III, IV or VI is elected, further election of a species is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-46, 55-69, 71-88 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
February 21, 2003